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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,211

10/21/2003

James Spitler

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04/21/2006

DALLAS OFFICE OF FULBRIGHT & JAWORSKI L.L.P.
2200 ROSS AVENUE
SUITE 2800
DALLAS, TX 75201-2784

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/690,211	Applicant(s) SPITLER ET AL.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,20-26,29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,20-26,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>see "Other"</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: PTO-1449 Mail Dates: 10/21/03, 6/14/04, 7/27/04, 3/14/05, 2/13/06 .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 3/22/2006 is acknowledged.

Claims 11-19, 27-28, and 31-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The examiner further acknowledges that these claims have been canceled by applicant. Election was made **without** traverse in the reply filed on 3/22/2006.

Specification

The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claims 3-6 are objected to because of the following informalities: There exists an inconsistency between the language of claim 3 and that of the claims 4-6 dependent thereon, thus making the scope of the claim unclear. In claim 3, line 1, applicant recites "the brace" with a mating receptacle being only functionally recited, i.e. "adapted for locking with a mating receptacle...", thus indicating that the claim is directed to the subcombination, "a brace". However, in claim 4, lines 7-9, applicant positively recites the receptacle as part of the invention, i.e. "the receptacle allows for...", thus indicating that the combination, brace and receptacle, is being claimed. Similarly, claims 5 and 6 positively recite the receptacle as part of the invention. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes the claims will be considered as being drawn to the combination, brace and receptacle.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 25, 26, 29 and 30 are being interpreted under 35 U.S.C. 112, sixth paragraph, means-plus-function language.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the structures" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitation "the distance" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 10, lines 1-2, applicant positively recites part of a human, i.e. " the structures are vertebrae". Thus claim 10 includes a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 20-22, 25, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Jammet (EP 1072228).

Jammet discloses embodiments of a medical implant system comprising a first bone anchor (ref. #1), a second bone anchor (ref. #2), and a brace (ref. #9/18) capable of coupling the first bone anchor to the second bone anchor. The brace has a distal end portion, which is capable of being pivotally and slidingly mated with a proximal end portion (ref. #7) of at least one of the bone anchors. The distal end of the brace is capable of transferring torque and compressive force from the brace to at least one of the bone anchors. The brace comprises a proximal end, the proximal end capable of locking with a mating receptacle (ref. #16) attached to the proximal end of the second bone anchor, the locking occurring when the distal end of the brace pivots with respect to the proximal end of the first bone anchor, the pivoting occurring while the distal end of the brace remains pivotally mated with the proximal end of the first bone anchor. The receptacle is capable of allowing polyaxial rotation with respect to the second bone anchor. The receptacle is a force fit with respect to the proximal end of the brace. The receptacle provides positive feedback when the proximal end of the brace is properly mated with the receptacle. The system further comprises a hinge (ref. #E2) attached to a proximal end of the first bone anchor for facilitating the pivotal mating. The hinge is capable of allowing for polyaxial rotation with respect to the first bone anchor. The proximal end of the brace is further capable of accepting torque applied thereto. The system is capable of being used in the vertebrae and the bone anchors are screws

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capable of being placed in the pedicle of the vertebrae. The hinge comprises proximal and distal openings (ref. #26) in-line from each other forming an in-line passage through the hinge; the distal opening comprising a clamp for rotatable attachment to the head of a bone anchor; the proximal opening capable of accepting the distal end of a brace prior to the bone anchor being secured in a bone, the hinge further comprising a pivot point capable of accepting a captured brace so as to allow the accepted brace to pivot with respect to the hinge but not to become released therefrom; and wherein the clamp allows the distal end of an accepted brace to become detachably coupled to the head of an attached anchor for the purpose of force transfer between the brace and the anchor. The proximal end of the hinge is further capable of accepting a force applying locking structure. The pivot includes at least one pair of bearings (ref. #27) positioned on either side of the in-line passage. The brace comprises a first key (ref. #53) at its distal end capable of releasably mating with a head of a first anchor so as to allow torque transfer between the brace and the first bone anchor; and a second key at its proximal end (ref. #41) capable of being releasably mating with a receptacle at a second one of the bone anchors. The shank further comprises at least one slot (ref. #10) longitudinally displaced along the shank in proximity to the distal end, the slot capable of accepting a fulcrum point affixed to the first anchor so as to allow the brace to pivot around the fulcrum point while still maintaining the shank in controlled spatial relationship with the first bone anchor. The brace comprises a curved shank portion (see curved portion, ref. #9)

Jammet et al. disclose a medical implant device comprising a first bone anchor, a second bone anchor, and a brace comprising a means for pivoting the brace from a first

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position to a second position (any mechanical motion of surgeon moving around the components of the device before they are connected) wherein in the second position the brace couples the first bone anchor to the second bone anchor, a means for slidably adjusting the means for pivoting along the longitudinal length of the brace (ref. #17), and a means for transmitting torque between the brace and the at least one of the bone anchors (ref. #18); the supporting means comprises a pair of bearings displaced on opposite sides of the captured brace, the bearings interfacing with the brace by indentations longitudinally displaced along the brace; the brace comprises means for engaging a receptacle attached to the second bone anchor spaced apart from the first bone anchor (ref. #18, end portion), the device further comprising means for polyaxially attaching the receptacle to the head of the second bone anchor (ref. #7); and wherein the receptacle comprises means for engaging with the brace; and the first and second anchor engagement means comprise means for locking the brace and the anchors in a fixed relationship with each other (ref. #6).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

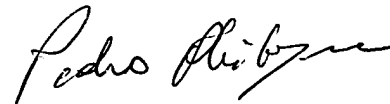
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCH



PEDRO PHILOGENE
PRIMARY EXAMINER